UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,253	11/04/2003	Pat D. O'Donnell	42581-P002P1	6108

7590 07/26/2007

Winstead Sechrest and Minick, P.C.
P.O Box 50784
Dallas, TX 75250-0784

EXAMINER	
HOPKINS, CHRISTINE D	
ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
07/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/701,253	O'DONNELL, PAT D.	
	Examiner	Art Unit	
	Christine D. Hopkins	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *9-17 and 20-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4 Nov 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 9-17 and 20-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 6, 2006.

Specification

2. The disclosure is objected to because of the following informalities: at page 1, lines 4-6, the current status of the parent application should be provided. Appropriate correction is required.

Claim Objections

3. Claims 2 and 18 are objected to because of the following informalities: at line 1 of claim 2, "wherein first handle further comprises" should apparently read --wherein said handle further comprises--; at line 2, "said digit accommodation" should apparently read --said digit control accommodation--. At line 11 of claim 18, "allowing allow the tip of the instrument" should apparently read --allowing the tip of the instrument--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 2 and 6-8 at line 1, it is unclear as to whether or not Applicant intends to claim the entire surgical instrument of claim 1 or only the subcombination of the "sling transfer instrument." Regarding claims 3-5 at line 1, it is unclear as to whether or not Applicant intends to claim the entire surgical instrument of claim 1 or merely the subcombination of the mesh sling.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 3, 5-7 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Staskin et al. (U.S. Pub. No. 2003/0045774). Staskin et al. (hereinafter Staskin) disclose surgical instruments and methods for introducing a sling into a patient suffering from urinary incontinence. Regarding claim 1, Staskin teaches a sling capable

of being applied to an area beneath and supporting the urethra or bladder neck [0118]. A "tissue remodeling portion" is attached to and surrounding a section of the sling [0117]. The "tissue remodeling portion" is interpreted as the sheath of Staskin since its purpose, as that of the instant application, is to provide strength and structural reinforcement to the sling [0117]. The sling supporting the urethra may be composed of a surgical mesh [0026]. Referring to Fig. 4, a sling transfer instrument defines a curved shaft portion **60** between distal and proximal ends, with an attached handle **64** at the proximal end and at the distal end, a dilator **54** for attaching the sling to the distal end of the shaft [0115].

With reference to claim 3, the polypropylene mesh, as taught by Staskin, contains filaments of woven material, each having a thickness of about .024 inches [0120].

Staskin discloses the dimensions of the sling, such dimensions being a length of "approximately" 60 cm and a width of 1.0 cm to 1.2 cm, thus capable of being "approximately" the widths specified at the central most portion and opposite ends of the sling according to claim 5 [0118].

With reference to claim 6, Staskin teaches that the shaft portion, or needle **60**, has a diameter of approximately 3.175 mm, or "about" 3.5 mm and less than 5.1 cm. Since the instant application provides no reason for a diameter of about 3.5 mm to about 4.0 mm, the dimensions of the needle as disclosed by Staskin are capable of transferring a sling to an implant site. Furthermore, regarding claim 7, the distal end of the shaft, or needle **60**, is oriented in a direction opposite of the curved portion (see Fig.

4). The distal end of the shaft portion is 1.0 cm, in length, since any length that is towards the distal end could be construed as such. As stated above, the width of the shaft is "approximately" 4mm.

Regarding claim 18, Staskin teaches a suprapubic method for applying a sling to a female for treating urinary incontinence. The sling supporting the urethra may be composed of a surgical mesh [0026] and a "tissue remodeling section" to provide strength and structural reinforcement to the sling [0117]. A sling transfer instrument having a curved shaft or needle **60** has an insertion handle **64**, adjusted to a surgeon's preference, and located at the instrument's proximal end [0218]. The surgeon holds the handle of the needle **60** and guides the needle through endopelvic fascia of the abdominal wall, using the pubic bone to guide the needle as the surgeon traverses the space approaching the vaginal incision ([0219]-[0222]). The steps are repeated with a second needle **60**. Once both needles are in place, a cytoscopy is performed to ensure that the bladder has not been punctured during implantation [0224]. The slings are associated with each end of the instruments or needles **60** via dilators **54** [0028]. The sling is placed in a therapeutically effective position, such as in support of the midurethra [0230]. In view of claim 19, once the sling is positioned under the midurethra, a "sling tension measurement component," or position adjustment member **66**, can be pulled by the surgeon in order to further position the sling or reduce the tension of the sling ([0231]-[0232]).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al. (U.S. Pub. No. 2003/0045774) in view of Bilbo (U.S. Pub. No. 2002/0103542). Staskin discloses the invention as claimed, see rejection supra; however Staskin fails to disclose the dimensions of the particular absorbable polymer utilized in the sling. Bilbo discloses a tissue engineered prosthesis, such as a sling, that may be implanted into a patient for the treatment of urinary incontinence. Regarding claim 4, Bilbo teaches the use of intestinal collagen, which is absorbable, as the construct for a sling supporting the bladder [0040]. The thickness is between about .2mm and .25mm, thus the filaments are "about" .012 inches. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have incorporated a bioabsorbable material, such as intestinal collagen as taught by Bilbo, to a mesh sling such as that disclosed by Staskin for implanting a sling that will, after a lapse in time, naturally degrade within the patient, yet provide support to the urethra for treating urinary incontinence prior to doing so.

10. Claims 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin in view of Inman et al. (U.S. Pub. No. 2003/0065246). Staskin discloses the

invention as claimed, see rejection supra; however Staskin fails to disclose specific dimensions of the indentations on the transfer handle for accommodating the fingers of a surgeon. Inman et al. (hereinafter Inman) disclose an instrument for introducing a sling into the pelvic area of a patient suffering from urinary incontinence. Regarding claim 2, Inman teaches a handle **12** having a "digit control accommodation," or channel **32** (see Figs. 2 and 3). The height of the handle is preferably between 3.25 in. to 4.75 in. [0046] whereby the width is preferably one-third of the height [0053]. Since the channel extends the width of the handle, the width of the "digit control accommodation" or channel **32** is about 1.08 in. to about 1.58 inches, thus falling within the range specified in claim 2. Furthermore, the length of the channel is approximately 1 in. [0051], and its depth is approximately one-half of the width [0053], thus the width, if it was 1.2 in, would bring the depth of the "digit control accommodation" to 0.6 in., or 1.5 cm in accordance with claim 2. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have fit a sling transfer instrument such as that disclosed by Staskin, to have the dimensions of the digit control accommodation as proposed by Inman, in an effort to provide a stable construction for a surgeon's finger when inserting a sling within a patient during a surgical procedure.

Regarding claim 8, Staskin discloses the invention as claimed, see rejection supra; however Staskin fails to disclose a transfer shaft for a sling having a luminous coating. Inman teaches a rod **14** of a transfer instrument (see Fig. 3) having a reflective coating for aiding visibility for the surgeon [0058]. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have coated a

transfer shaft, or needle, similar to that taught by Staskin, with a reflective or luminous material as suggested by Inman such that the instrument is easily viewed by the surgeon during application of a urinary incontinence sling within a patient.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6-8 and 10-11 of U.S. Patent No. 6,808,486. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims directed towards a surgical instrument for treating female urinary incontinence of the instant application are broader than the claims of the patent, also directed towards an instrument for treating female urinary incontinence, thus the claims of the patent anticipate those of the instant application.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pub. No. 2003/0171644 to Anderson et al. discloses a surgical instrument and implantation method for treating urinary incontinence.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735

Christine D Hopkins
Examiner
Art Unit 3735